REMARKS

Status of Claims and Amendment

Claims 1-8, 15, and 16 have been amended. Claims 1-6 and 16-18 are all the pending claims being examined in the application. Claims 7-15 and 19-28 are withdrawn as being drawn to a non-elected invention. Claims 1-6 and 16-18 are rejected.

Claims 1-8 and 16 have been amended to recite "an isolated protein" as suggested by the Office Action in response to a § 101 rejection. In addition, claims 1 and 5 have been amended to rephrase "derived from" with "obtained from" to further clarify that the claimed isolated protein is obtained from a microorganism belonging to genus Staphylotrichum. Support for the amendment to claim 1 may be found for example, at page 11, paragraph [0023] of the specification. Applicants note that one of ordinary skill in the art reading the specification, would recognize and understand Applicants' intent that the claimed isolated proteins are obtained from Staphylotrichum.

Claims 6 and 8 have been amended to delete reference to "deleted, substituted, inserted, or added." In addition, claim 6 has been amended to replace "homology" with "identity". Support for the amendment to claim 6 may be found for example, at page 13, paragraph [0031] of the specification.

Claims 7 and 15 have been amended to change the claim dependency from claim 1 to claim 6.

Claim 16 has been amended to incorporate the limitations of claim 15 and to depend from claim 6.

No new matter is added.

Drawings

Applicants thank the Examiner for indicating acceptance of the drawings filed June 5, 2006.

Claim of Priority

Applicants thank the Examiner for acknowledging the claim of priority to Japanese Application No. 2003-404020 filed December 3, 2003, as well as receipt of a copy of the priority document.

Information Disclosure Statements

Applicants thank the Examiner for acknowledging the Information Disclosure Statements (IDS) filed June 5, 2006, June 21, 2007, and February 25, 2008, by returning signed copies of the PTO/SB/08 forms submitted therewith.

Applicants note that although the Examiner has signed the bottom of each of the PTO/SB/08 forms submitted, the Examiner only initialed the reference cited in the IDS filed February 25, 2008. Accordingly, Applicants respectfully request that the Examiner clarify in the record that all references cited in the IDS filed June 5, 2006 and June 21, 2007, have been considered by returning, e.g., initialed and signed copies of the PTO/SB/08 forms submitted therewith.

Restriction Requirement

The Examiner has acknowledged Applicants' election with traverse of Group I (claims 1-6 and 16-18) in the Response filed February 25, 2008. The Examiner appears to maintain the restriction based upon the following rationale. The Examiner asserts that Applicants' arguments are not persuasive because the claims recite "derived from", instead of "isolated" or "obtained", so the claims appear to encompass any endoglucanase regardless of its amino acid sequence and

structure, and is not limited to an endoglucanase isolated from an microorganism belonging to the genus *Staphylotrichum*.

Thus, the Examiner concludes that the same or corresponding technical feature, i.e., a protein having endoglucanase activity, is shared among Inventions 1-3, and that Rasmussen et al (WO 91/17243; "Rasmussen") teaches a protein having endoglucanase activity. Accordingly, the Examiner asserts that because the technical feature is known in the cited art and makes no contribution over the cited art, the inventions are not linked as to form a single general inventive concept under PCT Rule 13.1. The Examiner has made the Restriction Final.

In response, Applicants note that solely to advance prosecution of the present application, the claims have been amended to replace "derived from" with "obtained from" *Staphylotrichum* in order to further clarify that the claims encompass a protein having endoglucanase activity which is obtained from *Staphylotrichum*. In this regard, Applicants note that the claimed invention is not disclosed by Rasmussen which only discloses a protein obtained from *Humicola insolens*.

Accordingly, because the same or corresponding technical feature is shared among Inventions 1-3, and the technical feature of the claimed invention makes a contribution over Rasmussen, the claimed inventions are linked to form a single general inventive concept under PCT Rule 13.1. Applicants respectfully request withdrawal of the restriction requirement, and that the non-elected claims be rejoined for examination in the present application.

Response To Claim Objections

Claim 16 is objected to for depending from nonelected claim 15. The Office Action asserts that Applicants are required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

In response, and solely to advance prosecution of the present application, claim 16 has been amended to incorporate the limitations of claim 15.

Withdrawal of the grounds of objection is respectfully requested.

Response To Claim Rejections Under 35 U.S. C. § 101

Claims 1-6 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

The Office Action appears to assert that the claims do not distinguish over naturally-occurring proteins, and suggests that the rejection may be addressed by amending the claims to recite "an isolated protein."

In response, and solely to advance prosecution of the present application, the claims have been amended to recite "an isolated protein, as suggested by the Office Action.

Withdrawal of the rejection under § 101 is respectfully requested.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

1. Enablement

Claim 6 is rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. It appears that while the Office Action considers the specification to be enabling for an isolated protein comprising the amino acid sequence of SEQ ID NO: 3 and having endoglucanase activity, the Office Action asserts that the specification does not enable one of ordinary skill in the art to make a modified protein having endoglucanase activity and comprising an amino acid sequence in which 1-30 amino acids are deleted, substituted, inserted or added to SEQ ID NO: 3, and any homologous protein having endoglucanase activity and comprising an amino acid sequence having at least 85% homology to SEQ ID NO: 3.

The Office Action appears to assert that although methods for isolating or generating variants and mutants using random mutagenesis techniques were known in the art, neither the specification nor the state of the art at the time the invention was made provides the necessary guidance for altering the amino acid sequence of SEQ ID NO: 3 without undue experimentation. The Office Action appears to assert that the specification does not provide sufficient guidance or any working examples regarding the structures involved in the function of the claimed proteins. In this regard, the Office Action asserts Chica et al. (Curr. Opin. Biotechnol. 2005 16(4): 378-84) for the proposition that enzyme modification requires an understanding of the structure/function relationships.

The Office Action asserts that there is a high level of unpredictability associated with making modifications to a polypeptide sequence, as evidenced by Witkowski et al (Biochemistry. 1999 Sep 7; 38(36): 11643-50) and Seffernick *et al.* (J Bacteriol. 2001 Apr; 183 (8): 2405-10). Witkowski is asserted by the Office Action for the proposition that a single amino acid substitution results in a change of the activity of a polypeptide, while Seffernick is asserted for the proposition that two proteins with 98% amino acid sequence identity may have different functions.

Therefore, in view of the asserted overly broad scope of the claims, the specification's lack of specific guidance and additional working examples, the high level of unpredictability as evidenced by the prior art, and the amount of experimentation required, the Office Action asserts that it would require undue experimentation for a skilled artisan to make and use the entire scope of the claimed invention.

Initially, Applicants note that under standard U.S. practice, "[d]etailed procedures for making and using the invention may not be necessary if the description of the invention itself is

sufficient to permit those skilled in the art to make and use the invention" (see M.P.E.P. §2164) "[a]s long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim" (see M.P.E.P. §2164.01(b)). Further, the Board of Patent Appeals and Interference (BPAI) has concluded that while the amount of experimentation required to practice the full scope of an invention was considerable, such experimentation was routine in the art and not "undue." Ex parte Kubin (BPAI 2007) (the application claimed the genus of all sequences with 80% similarity to the identified sequence that maintained functionality and the BPAI noted that the disclosed methods is common in molecular biology applications as minor changes in gene sequences can still have the same function as the unaltered sequence.). Accordingly, the BPAI has recognized that mere routine experimentation is required to enable the full scope of an Applicants' claims reciting nucleic acids encoding proteins at least 80% identical to the disclosed amino acid sequence claimed. Thus, the BPAI has found that claims having scope broader than the exact amino acid or nucleotide sequence disclosed should not be rejected under the enablement requirement of 35 U.S.C. § 112, first paragraph.

Accordingly, "[t]he fact experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." M.P.E.P. §2164.01. In other words, the specification does not need to contain an example if the invention is disclosed in a manner as to allow one skilled in the art to practice it without undue experimentation. M.P.E.P. §2164. Further, "[t]he scope of enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required." M.P.E.P. §2164.03. Also, the absence of a working example will not by itself render the invention non-

enabled, and the lack of working examples or lack of evidence that the claimed invention works as described is insufficient grounds for a lack of enablement rejection. M.P.E.P. §2164.02.

In this regard, Applicants note that the specification at the paragraph bridging page 12 to 13 discloses that a modified protein of the claimed invention may be made by deleting, substituting, inserting, or adding 1 to 30 amino acids contained in a catalytic domain, linker region, or cellulose-binding domain of SEQ ID NO:3. With regard to substitutions, the specification discloses that "conservative substitutions" may be made in which amino acids contained in the protein are replaced with amino acids having similar chemical properties so that the activities of the protein are not substantially changed. (See page 13, 1st full paragraph of the specification). For instance, the specification teaches that hydrophobic amino acids may be substituted for each other. Likewise, polar amino acids, basic amino acids, or acidic amino acid may be substituted for each other in their respective groups. In addition, page 24, 5th full paragraph and Figures 1 and 2 of the specification discloses that the catalytic domain is encompassed by amino acids corresponding to amino acids 1 to 207 of SEQ ID NO:3, the linker region is encompassed by amino acids corresponding to amino acids 208 to 258 of SEQ ID NO:3, and the cellulose-binding domain is encompassed by amino acids corresponding to amino acids 259 to 295 of SEQ ID NO:3.

It would be within common technical practice for one skilled in the art to perform a homology search or alignment to determine the degree of similarity between the sequences disclosed, and to surmise from the homology search or alignment, the regions of conserved amino acids that are important for function without undue experimentation. As disclosed at the bottom of page 13 of the present specification, one skilled in the art would understand and surmise based on common technical knowledge and common sense, e.g., determination of

homology in the amino acid sequence based on a FASTA3 calculation or BLAST search algorithm, and the disclosure in the specification, how to make and use the claimed isolated protein comprising an amino acid sequence having at least 85% identity to SEQ ID NO:3.

Accordingly, reconsideration and withdrawal of the rejection under § 112, first paragraph, is respectfully requested.

2. Written Description

Claims 1, 5, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement.

The Office Action appears to be asserting that because claims 1 and 5 recite "derived from", instead of "isolated" or "obtained", then the claims broadly encompass any endoglucanase regardless of its amino acid sequence and structure, and is not limited to an endoglucanase isolated from *Staphylotrichum*. Accordingly, the Office Action's rationale for the written description rejection appears to be similar to the rationale for the enablement rejection, i.e., the claims encompass a genus of proteins having endoglucanase activity from any biological source comprising any amino acid sequence and structure.

The Office Action asserts that the written description requirement may be satisfied through sufficient description of a representative number of species or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics.

In response, and solely to advance prosecution of the present application, claims 1 and 5 have been amended to rephrase "derived from" with "obtained from" and to recite "an isolated protein." One skilled in the art reading the specification, would recognize and understand

Applicants' intent that the claimed isolated proteins are obtained from Staphylotrichum. In addition, claim 16 has been amended to recite positive steps involved in the process of producing the claimed isolated protein, i.e., to incorporate the limitations of claim 15 and to depend from claim 6.

Accordingly, reconsideration and withdrawal of the rejection under § 112, first paragraph, is respectfully requested.

Response To Claim Rejections Under 35 U.S.C. § 102

Claims 1, 5, and 16-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rasmussen.

The Office Action appears to assert the same reasons as set forth above, i.e., that because claims 1 and 5 recite "derived from", instead of "isolated" or "obtained", the claims encompass any endoglucanase regardless of its amino acid sequence and structure, and are not limited to an endoglucanase isolated *Staphylotrichum*.

With regard to claim 16, the Office Action asserts that no patentable weight is given to the process for making the endoglucanase since there are no structural difference between the produced protein of claim 16 and the protein disclosed by Rasmussen.

In response, Applicants note that as previously argued, Rasmussen does not explicitly or inherently disclose the presently claimed isolated protein having endoglucanase activity obtained from *Staphylotrichum*. The 43 κD endoglucanase disclosed in Rasmussen was derived from *Humicola insolens*, and has the amino acid sequence of SEQ ID NO:2 (305 amino acids) as shown in the Sequence Listing appended to Rasmussen.

Reconsideration and withdrawal of the rejection under § 102(b) is respectfully submitted to be proper.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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